

BY 45. The method of claim 38 or 40, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.

46. The method of claim 45, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor.

REMARKS

This Amendment is respectfully submitted in response to the Final Rejection rendered September 7, 2001. It is timely in view of the Petition for Extension of Time submitted concurrently herewith. A Notice of Appeal has been submitted concurrently herewith in order to maintain the pendency of this application. Applicants respectfully submit that the foregoing amendments to the claims places the application in better condition for allowance or appeal and therefore, this Amendment should be entered.

The claims have been amended above to include the clause "containing soybean trypsin inhibitor" in claims 30, 45 and 46 in order to clarify that which the inventors consider to be their invention. Basis for these amendments can be found in the Specification at p. 16, l. 12-29 and p. 25, l. 10-15. The claims have also been amended to include the clause "cells in need thereof", referring to cells needing phagocytosis modulation, in order to clarify the method of applicants' invention. Claims 23, 24, 37, 38, 39 and 40 have been so amended. These amendments find basis in the Specification at p. 20, l. 30-35. Claims 37-40 have been amended in order to indicate that such soybean milk is, in accordance with the method of applicants' invention, applied topically to mammals. These amendments find basis in the Specification at p. 21, l. 19-21. Claims 23, 24, and 37-40 have been amended to add the term "therapeutically phagocytosis- or ICAM-1-increasing or decreasing" amount. Basis may be found for these additions in the Specification at p. 24, l. 20-21. A marked-up copy of the claims as amended is attached hereto as an appendix.

Claims 1-22, 26, 27, 42, 43 and 59-74 have been canceled without prejudice in light of the restriction requirement and species election requirement. The claims have also been amended to remove reference to non-elected subject matter and embodiments as required in the Final Rejection. Applicants will file a divisional application containing the canceled subject matter.

Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47, 58 and 70-74 have been rejected provisionally under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-60 of copending application Serial No. 09/110,409. Applicants respectfully offer that, should claims become allowed, appropriate action will be taken with respect to this provisional rejection.

The Final Rejection contained rejections based upon 35 U.S.C. 102(b) and (e) and 103(a). Claims 2, 4, 8-21, 24, 28-35, 38, 40 and 44-47 were rejected under 35 U.S.C. 102(b) as being anticipated by Limtrakul et al. Claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 were rejected under 35 U.S.C. 102(b) in view of Kosaka. Claims 2, 4, 8-22, 24, 28-36, 38, 40 and 44-47, 58 and 70-74 were rejected under 35 U.S.C. 102(b) as being anticipated by JP 62036304. The claims were also provisionally rejected under 35 U.S.C. 102(e) as being anticipated by copending U.S. Patent Application Serial No. 09/110,409, if patented. The Final Rejection also rejected claims 2, 4, 8-22, 24, 28-36, 38, 40, 44-47 and 58 under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. taken with Kosaka or JP 62036304. Claims 70-74 were rejected under 35 U.S.C. 103(a) as being unpatentable over Limtrakul et al. or Kosaka taken with JP 62036304. Applicants respectfully requests reconsideration of these rejections in view of the foregoing amendments to the claims and the ensuing discussion.

1. None of the References Cited Suggests or Discloses a Method of Affecting Phagocytosis

Applicants respectfully point out that none of the cited references, Limtrakul et al., Kosaka, the "304" abstract, nor the earlier-filed patent application, suggests or discloses a method of affecting phagocytosis. As to claims 2, 4, 8-21, 26, 27, 42, 43 and 59-74, which have been canceled without prejudice, applicants respectfully assert that the rejection herein is moot. Taken separately or together, the cited references neither anticipate nor render obvious the methods of applicants' invention.

Limtrakul et al. relates to the "suppressive effect of soybean milk protein on experimentally induced skin tumor in mice" [Limtrakul, et al., p. 1]. Limtrakul does not mention topical application of soybean milk to mammals or humans. Rather, Limtrakul et al. teaches **the inclusion of soybean milk in the diet of mice** for the purpose of suppressing skin tumor growth and occurrence. Applicants respectfully submit that, in view of the foregoing amendments, Limtrakul et al. does not anticipate the claims as amended.

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Kosaka, likewise, does not suggest or describe the topical application of soybean milk to the skin, as admitted in the Final Rejection. Furthermore, Kosaka **nowhere** mentions phagocytosis or the application of soybean milk to affect phagocytosis to cells that require modulation of phagocytosis. Thus, Kosaka does not anticipate the claims as amended. Nor does the 304 abstract suggest or disclose a method of affecting phagocytosis. It merely states that a type of soybean milk "is useful as cosmetic for skin and hair..." [304 Abstract]. *inherent*

Moreover, the earlier-filed patent application, Serial No. 09/110,409, does not mention at any point the method of using soybean milk to affect phagocytosis in cells in need thereof. Thus, applicants respectfully submit that the rejection based upon the descriptions set forth in the cited references should be reconsidered. *A*

2. The Cited References Do Not Suggest or Describe the Topical Use of Soybean Milk Containing Soybean Trypsin Inhibitor

Applicants respectfully submit that the cited references are insufficient to suggest or disclose to one of ordinary skill in the art the embodiments of their invention. Either they do not refer to topical use of soybean milk, as admitted in the Final Rejection, or, if they refer to soybean milk, the soybean milk to which they refer would **not** have contained active proteins such as soybean trypsin inhibitor ("STI") and the like. The Limtrakul et al. and Kosaka references cited do not teach or contemplate topical use of soybean milk at all [Final Rejection, page 6]. The 304 abstract, as demonstrated below, does not suggest or describe the use of soybean milk that has not been denatured of its protein content.

While the 304 abstract does include reference to cosmetic application of soybean milk, applicants respectfully urge that (1) a review of the full disclosure represented by the abstract indicates that, indeed, the soybean milk used therein was subjected to heat; and (2) those of ordinary skill in the art at the time the invention was made would have interpreted the cited references' allusion to "soybean milk" as having been heat-treated or otherwise treated to remove soybean trypsin inhibitor. *7*

Applicants respectfully attach hereto a copy of a translation of Japanese Kokkai No. 62-36304. Applicants respectfully draw the attention of the Patent and Trademark Office to the translated description at page 2, lines 7-9, as follows:

The object of this invention is "soybean milk," which is an emulsion that is obtained by aqueous extraction of soybean seeds, grinding them after they have swollen, adding water to them **and heating them** and separating the insoluble residue by filtration... [Kokkai No. 62-36304, p. 2, l. 7-9] (emphasis added)

Furthermore, in the examples, at page 5, lines 6-14, a commercial preparation of soybean milk is further heated "over a **hot bath** for 30 minutes" (emphasis added) in making the described cosmetic formulation [Kokkai No. 62-36304, p. 5, l. 9]. Moreover, commercial preparations of soybean milk intended for ingestion would have been treated prior to public sale in order to denature any proteins harmful to digestion. Thus, applicants respectfully submit that the 304 abstract was intended to describe soybean milk that had been heat-treated, which would have caused the denaturation of STI and like proteins.

Even if the 304 abstract had been taken alone without reference to the full Kokkai description, one of ordinary skill in the art would have understood the reference to "soybean milk" as meaning soy milk that had been denatured of its protein content. As set forth in the Declaration of Katharine Martin, attached hereto, it was well-known to those of skill in the art that soybeans were not originally consumed as food "due to serious gastric distress that resulted from eating the raw bean" [Declaration of Katharine Martin, ¶4]. Only once fermentation and precipitation techniques were developed that inactivated proteins present in the soybean, including STI, were soybeans able to be consumed [Declaration of Katharine Martin, ¶4]. Ms. Martin cites several studies that demonstrate the negative effects of native STI to the digestive system [Declaration of Katharine Martin, ¶5]. Thus, applicants respectfully submit that one of ordinary skill in the art, reviewing the cited 304 abstract, would have understood its reference to "soybean milk" as a denatured product that would not have contained STI or like proteins.

Thus, even in the context of the 304 Abstract, those of ordinary skill in the art would not have understood the cited reference to contain STI or other active proteins.

3. U.S. Serial No. 09/110,409 Does Not Disclose or Suggest The Method of Applicants' Invention

The previously-filed patent application, U.S. Serial No. 09/110,409 ('409 application), neither suggests nor describes the methods of applicants' invention. The '409 application describes soybean milk-containing compositions, however, it does not recognize the need for

modulating phagocytosis nor does it indicate such compositions should be applied to cells in need of phagocytosis modulation. Thus, it is not sufficient as a reference under 35 U.S.C. 102(e).

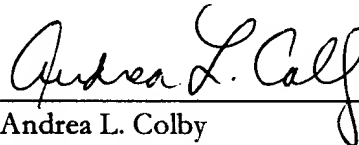
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4. The Cited References, Taken Separately or Together, Neither Anticipate Nor Render Obvious the Methods of Applicants' Invention

Applicants respectfully submit that, as none of the references cited even refer to phagocytosis and methods of modulating phagocytosis, none anticipates the claimed methods of applicants' invention. Even if the cited references were combined, they would be insufficient to lead one of ordinary skill in the art to the methods of applicants' invention: Limtrakul et al. and Kosaka do not even mention topical application of soybean milk and the 304 Abstract and full disclosure teaches the application of heat-treated soybean milk, nowhere recognizing the ability of soybean milk containing STI to effect changes in phagocytosis of cells needing to have such treatment. Thus, the cited references neither anticipate nor render obvious the claims of applicants' invention.

Applicants respectfully request reconsideration of the rejections set forth in the Final Rejection in light of the foregoing amendments to the claims and discussion. An early allowance is earnestly solicited.

Respectfully submitted,



Andrea L. Colby
Attorney for Applicants
Reg. No. 30,194

Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003
(732) 524-2792
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APPENDIX – MARKED-UP CLAIMS

23. (Amended) A method of increasing phagocytosis or ICAM-1 expression in a mammalian cell in need thereof, comprising contacting the cell with [an] a therapeutically phagocytosis- or ICAM-1-increasing effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically increases phagocytosis or ICAM-1 expression.
24. (Amended) A method of decreasing phagocytosis or ICAM-1 expression in a mammalian cell in need thereof, comprising contacting the cell with [an] a therapeutically phagocytosis- or ICAM-1-decreasing effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
30. (Amended) The method of claim 29, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor[, soybean paste, Compound I, a trypsin inhibitor, a tryptase inhibitor, a thrombin inhibitor and STI].
37. (Amended) A method of treating a mammal afflicted with a disorder ameliorated by an increase in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells [mammal] in need thereof a therapeutically phagocytosis- or ICAM-1-increasing effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically increases phagocytosis or ICAM-1 expression.
38. (Amended) A method of treating a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells [mammal] in need thereof a phagocytosis- or ICAM-1-decreasing therapeutically effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.
39. (Amended) A method of preventing a mammal afflicted with a disorder ameliorated by an increase in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells [mammal] in need thereof a prophylactically phagocytosis- or ICAM-1-increasing effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically increases phagocytosis or ICAM-1 expression.
40. (Amended) A method of preventing a mammal afflicted with a disorder ameliorated by a decrease in phagocytosis or ICAM-1 expression in appropriate cells, which comprises topically administering to the cells [mammal] in need thereof a prophylactically phagocytosis- or

ICAM-1-decreasing effective amount of [an agent] soybean milk containing soybean trypsin inhibitor that specifically decreases phagocytosis or ICAM-1 expression.

45. (Amended) The method of claim 38 or 40, wherein the agent is selected from the group consisting of [a] soybean milk containing soybean trypsin inhibitor [soybean derivative and a serine protease inhibitor].

46. (Amended) The method of claim 45, wherein the agent is selected from the group consisting of soybean milk containing soybean trypsin inhibitor[, soybean paste, Compound I, a trypsin inhibitor, a tryptase inhibitor, a thrombin inhibitor and STI].